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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Michael E. McCadden Art Unit 1615
Serial No. 09/652,381
Filed August 31, 2000
For COMPOSITION FOR THE TOPICAL TREATMENT OF RASHES, DERMATOSES AND LESIONS

DECLARATION OF MICHAEL E. McCADDEN

I, Michael E. McCadden, declare as follows:

1. I am the sole inventor of the subject matter claimed in above-identified U.S. Patent Application No. 09/652,381, filed August 31, 2000.

2. I am a practicing Dermatologist in St. Louis, Missouri. I received my medical degree from Vanderbilt University Medical School in Nashville, Tennessee in 1982. From June, 1982 to June, 1984, I was an intern and resident in Internal Medicine at Indiana University Medical Center in Indianapolis, Indiana. From July, 1984 to June, 1988, I was a resident in dermatology and then an Instructor in the Division of Dermatology at Vanderbilt University Medical Center.

3. While a dermatology resident at Vanderbilt, the chief of Dermatology, Lloyd E. King, Jr., M.D. suggested that the following shake lotion formulation be prescribed for a patient we were treating who presented with a red moist oozing rash distributed over both inguinal creases extending into the groin: hydrocortisone (1% by weight), nystatin (about 500,000 units to the best of my recollection), and calamine lotion (4 ounces). To the best of my recollection, I subsequently prescribed this shake lotion formulation to various patients presenting with intertrigo, diaper rash, yeast infections and contact dermatitis other than Rhus induced contact dermatitis (e.g., poison ivy and poison oak) involving the genital and groin region during my residency at Vanderbilt and, depending upon the severity of the patient's skin disease, I varied the concentration of

hydrocortisone from 0.5% by weight to 1% by weight and I varied the concentration of nystatin from 500,000 units to 1,000,000 units in four ounces of calamine lotion. I have no recollection of the number or identity of the patients I treated with these formulations while at Vanderbilt.

4. When I began my Dermatology practice in St. Louis, Missouri in June, 1988, I continued to prescribe the shake lotion I prescribed while at Vanderbilt and, to the best of my recollection, I prescribed this shake lotion formulation to various patients presenting with intertrigo, diaper rash, yeast infections, tinea infections, balanoposthitis, lichen simplex chronicus, and contact dermatitis other than Rhus induced contact dermatitis (e.g., poison ivy and poison oak) involving the genital and groin region and, depending upon the severity of the patient's skin disease, to the best of my recollection I varied the concentration of hydrocortisone from 0.5% by weight to 2% by weight and I varied the concentration of nystatin from 500,000 units to 1,500,000 units in four ounces of calamine lotion. I have no recollection of the number or identity of the patients I treated with these formulations in the course of my dermatology practice in St. Louis.

5. One of the limitations with these formulations which I prescribed while in my residency at Vanderbilt and in my practice in St. Louis is that the antifungal coverage of nystatin is not sufficiently broad spectrum. Nystatin only treats yeast (Candida) infections. In mixed infections, therefore, where dermatophyte infections are present, the shake lotion formulations containing hydrocortisone, nystatin and calamine did not provide a full spectrum of activity.

6. After September 30, 1998, I began prescribing shake lotion formulations to patients containing hydrocortisone 1% by weight, clotrimazole 1% by weight, and calamine lotion (4 ounces). This formulation provides a significantly broader

spectrum of activity, thereby greatly increasing its efficacy for certain disease states.

7. I declare that all statements made herein of my knowledge are true; and further that these statements were made with the knowledge that willfully making false statements is punishable by fine, imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

January 5, 2001
Date

Michael E. McCadden, M.D.